

Health Information Technology Policy Committee
Final
Summary of the June 25, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 13th meeting of the Health Information Technology Policy Committee (HITPC), reminded the group that this was a Federal Advisory Committee meeting and therefore was being conducted in public, and conducted roll call.

2. Review of the Agenda

HIT Policy Committee Co-Chair Paul Tang reviewed the meeting's schedule, which was rearranged somewhat to accommodate the travel schedules of some participants. The group approved the minutes from the last HITPC meeting (held on May 19, 2010).

Action Item #1: The Committee approved the minutes from last HITPC meeting, held May 19, 2010, by consensus.

3. Opening Remarks

National Coordinator for HIT David Blumenthal explained that the HITPC's efforts are in a period of winding up of the first set of meaningful use standards and certifications, and looking ahead to the next phase. Meanwhile, the Committee must pay attention to all manner of continuing issues. Work continues on privacy and security, and they must prepare for a possible rule on governance of the National Health Information Network (NHIN), which Congress has tasked them with considering. Work also continues on the substrate for interoperability in the health system through the NHIN and its standards, policies, and implementation specifications. He expressed gratitude for the hard work and dedication of the Committee.

4. ONC Update: NHIN Direct - Standards and Interoperability Framework

Doug Fridsma of ONC explained that the Office is working to support the lifecycle of standards and interoperability. There are Meaningful Use criteria that this Committee will establish, and as a result, standards that will be implemented into technologies and used in certification criteria. Many things happen between the time that policy decisions are made and standards are constructed. He said he hopes to give the Committee a sense of some of the activities that occur in between, and an understanding of the coordination that is necessary.

Doug Fridsma characterized an implementation specification as a recipe. It tells people how to build software to do certain things. Policies have to be translated into these recipes. The goal is

to create reproducible recipes and develop tools that increase their efficiency in building these recipes. Therefore, computational approaches are needed.

ONC also is working on linking use cases so that there is no break in the chain from the high-level policy objectives all the way through specific standards and certification criteria. ONC is working with the National Institute of Standards and Technology (NIST) on this effort. If there are specific requirements that are translated into these recipes, then tools can be built to make it easier for companies to create things that will stand up to the criteria. This framework is intended to address whatever standards might be developed in the future, with initiatives such as the NHIN Direct, the interoperability framework, and focused collaboration.

The first step will be to examine what needs to be accomplished and deconstruct it into the data needed as well as the functions to be performed. Use cases will crop up from various sources; each of which will be broken down in this manner. Doug Fridsma used e-prescribing as an example of use case development. The National Information Exchange Model will be used. Paragraph descriptions will be broken down into data and function, harmonized, and all of the pieces will be able to function together.

Doug Fridsma emphasized the importance of these activities not occurring in the abstract. There must be a quality check for implementation specifications: they will have to actually build it, to have a “test kitchen” to make sure the recipe is correct. Pilot projects and demonstrations will be initiated; one of the first use cases that will be put through this framework is the NHIN Direct project.

In discussion, the following was noted:

- Paul Eggerman pointed out that although certification is the final step in ONC’s process, it is the starting point for industry. Once vendors have the certification criteria, it takes 1 or more years to develop a product. Then, it must be certified, marketed, and distributed to customers. Therefore, it is important that this work be coordinated with the timeline of the Phase 2 certification process. He asked how ONC is coordinating this work so that it is done in time for industry to use it. Doug Fridsma explained that given the time constraints, ONC does not plan to wait to engage NIST and those who will be helping to implement testing strategies. It is hoped that NHIN Direct will be ready for an HIT Standards Committee (HITSC) review in January 2011.
- Gayle Harrell commented on the extremely ambitious timeline associated with these efforts. Given that early adopter hospitals are going to start purchasing systems in 2010, this work will not be available to benefit those who are going to start purchasing systems. Doug Fridsma explained that the work that is already in place for 2011 will need to be backfilled into this process. The directives for meaningful use that have come from this Committee, and the standards required to support them, already exist. As they look ahead to 2013, 2015, and beyond, at some point they have to make sure they have the integration that needs to occur. It will take some time to get to that point, but they must start building the framework so that when data starts being reused for clinical decision support, etc., that there is consistency across the standards. The only way to do that is to start now and think ahead.

- David Blumenthal acknowledged that the questions regarding timeframe are important. One of the reasons this Committee was relatively modest in its recommendations around exchange had to do with its recognition that the work associated with exchange issues is still incubating. Therefore, compromises were made on the aspirations for the first stage of meaningful use. In fact, the first stage only requires the demonstration of a capability. The capabilities requirements of the systems that are purchased will have to be continuously upgraded. That represents a significant challenge, and vendors will need to be able to mature their products after they are installed. Some vendors will be better at this process than others, and hopefully that will be part of the discussion as systems are acquired.

5. NHIN Governance

Mary Jo Deering of ONC asked the Committee for help in establishing the governance of NHIN. This issue is essential to establishing trust in information exchange. ONC will release an initial Request for Information in early August and will publish a Notice of Proposed Rulemaking (NPRM) in early 2011, with a final rule expected by next summer. She presented some rhetorical questions to HITPC members, such as is this what ONC should be asking? What should ONC be asking?

A single line in the Health Information Technology for Economic and Clinical Health (HITECH) Act indicates that ONC is to establish a governance mechanism for the NHIN by rulemaking. ONC must be sure that users have trust in how information is shared, and be confident that the system works. Without governance, NHIN exchange cannot expand beyond the legal guidelines and baseline of governance that currently exists. Complimentary mechanisms are being sought to fill the gap. An HIT trust framework would be useful; Mary Jo Deering presented five categories of attributes that are needed for trust: (1) agreed-upon business, policy, and legal requirements; (2) transparent oversight; (3) enforcement and accountability; (4) identity assurance; and (5) technical requirements. It is premature to know whether these five categories will frame the rule itself. They do represent an effective starting point, however, for HITPC discussion. She noted that there also are questions of scope (e.g., should the NHIN be “branded,” should any use of the NHIN standards lie outside of governance, when should the governing levers that do exist be used?).

The ensuing discussion included the following points:

- David Blumenthal noted that this discussion begins with a task assigned by Congress: ONC shall establish a governance mechanism for the NHIN. This discussion also needs to take place due to the broader mandate to create a broad, secure health information system. His sense is that this will not happen by itself, that there will be a continuing need for an organizing force. The issue is made more urgent because there is a group of organizations that are now trying to use the NHIN to exchange data. They are trying to decide how to move forward on a set of technical and legal issues, and the General Counsel has ruled that they cannot do much without ONC input.
- Gayle Harrell proposed that the Committee designate a significant amount of time during a future HITPC meeting to discuss this topic. Mary Jo Deering indicated that ONC will ask both

the HITPC and HITSC to hold full joint hearings in early September. Meanwhile, she will be working with the tiger team in August on privacy and security-related issues.

- LaTanya Sweeney commented on two different methods of governance: a hands-off approach to governance versus complete command and control. She noted that another model has worked effectively, which is a climate that allows a lot of freedom, but in fact provides the right kind of technical and policy incentives that could create a convergence. She used the world wide web as an example. She discussed an example, when the Commerce Department indicated that it did not have the authority to force a standard for credit cards. A group of academics and institutions collaborated, formed a consortium, and as a group with the right experts and right focus, tackled the issue. Their work came together very quickly, and within a year people were using and trusting the world wide web.
- Neil Calman about what type of responsibility the HITPC and ONC have to ensure that during the implementation effort, groups are not spending a significant amount of resources on systems and vendors that might not be able to upgrade their systems as necessary. He suggested it might be important to define some quantum dates, as they have done with meaningful use. In this way, there will at least be some sense of stability at certain points along the timeline.

6. Meaningful Use Workgroup: Disparities Hearing Briefing

Meaningful Use Workgroup Co-Chair George Hripcsak discussed a hearing that was held on June 4 on the topic of eliminating disparities, with a focus on finding solutions. The Workgroup held two previous hearings, with experts providing testimony on disparities and related problems. The June 4 hearing included panels on health literacy and data collection, culture, and access. Disparities in the following areas were discussed: (1) race and ethnicity, (2) language, (3) health literacy, (4) migrant and seasonal workers, (5) children and the elderly, and (6) the homeless.

“The underserved” does not represent one group of people. It is a number of groups, and a solution for one group may not be the solution for another. It is important to engage the community in the design of solutions to their problems. George Hripcsak commented that it is necessary to develop a sensitivity to the issues of underserved populations, and to recognize that one or two policies will not solve the problem.

A common theme surfaced during the hearing—the importance of communication and sharing information. It is necessary not just to look at disparities but to report them, so that it is possible to judge how well they get addressed. Education and training will be necessary to address disparities, as well as the trust of the community.

On July 29, the Meaningful Use Workgroup will hold a hearing on population and public health. On August 5, a hearing on care coordination is planned.

Neil Calman noted that another issue that arose during the June 4 hearing was the responsibility to make sure that safety net providers are not left behind as electronic health records (EHRs) are implemented. The HITPC should be monitoring the implementation rate among safety net

providers; otherwise, their patients will continue to have disparities as effort rolls out. Also, he indicated that he has received a number of e-mails since the hearing regarding disparities around treatment based on sexual orientation and gender identity.

A discussion followed the presentation, and included these highlights:

- Marc Overhage emphasized that these disparities need to be addressed. The sooner standards can be put into place for what data needs to be collected, the sooner they can start to manage what seems to be a solvable problem.
- David Blumenthal noted that ONC has identified this as a priority area, and is trying to develop approaches to assuring that its activities do not enhance disparities, and, preferably, reduce them. He added that technology tends to be adopted first by majority groups.
- Gayle Harrell said that in Florida, many safety net hospitals are underfunded. If they have large residency programs and clinics, then the question of whether their physicians have separate ID numbers becomes an issue. Safety net hospitals need to be examined in a separate category, because they are facing significant challenges.
- Committee members discussed how safety net hospitals and clinics should be defined. Many facilities truly work with underserved populations, and they see themselves as safety nets although they may not have been identified as such by any group. The ability to identify who they are would be very helpful.

7. Privacy and Security Tiger Team Update and Recommendations

Paul Egerman presented update for the Privacy and Security Workgroup's tiger team, which has a schedule of topics to be addressed this summer. The first topic the tiger team addressed was message handling in directed exchanges. Message handling involves messages that go from one health care entity's computer to another in the process of treating a patient. One example is the ordering of a lab test. The team established two primary questions regarding directed exchange: What are the policy guardrails for message handling in directed exchange? Who is responsible for establishing "trust" when messages are sent?

Four categories of message handling also were identified:

- Model A - No intermediary is involved (exchange is direct from message originator to message recipient).
- Model B - The intermediary only performs routing and has no access to unencrypted personal health information (PHI) (the message body is encrypted and the intermediary does not access unencrypted patient identification data).
- Model C - The intermediary has access to unencrypted PHI (i.e., the patient is identifiable) but does not change the data in the message body.

- Model D - The intermediary opens message and changes the message body (format and/or data).

The tiger team offered a series of recommendations regarding directed exchange, as follows:

- Unencrypted PHI exposure to an intermediary in any amount raises privacy concerns.
- Fewer privacy concerns for directed exchange are found in models in which no unencrypted PHI is exposed (i.e., models A and B). ONC should encourage the use of such models.
- Models C and D involve intermediary access to unencrypted PHI, introducing privacy and safety concerns related to the intermediary's ability to view and/or modify data. Clear policies are needed to limit the retention of PHI and restrict its use and re-use.
- The team may make further privacy policy recommendations concerning retention and reuse of data. Model D also should be required to make commitments regarding accuracy and quality of data transformation.
- Intermediaries who collect and retain audit trails of messages that include unencrypted PHI should also be subject to policy constraints.
- Intermediaries that support models C and D require contractual arrangements with the message originators in the form of Business Associate agreements that set forth applicable policies and commitments and obligations.

The team also discussed who should be responsible for establishing exchange credentials. The sender has to authenticate the receiver. How does the sender know that the message will get to the right place? A digital credential is a certificate assigned to the computer so that when the machines talk to each other they can validate that they are the correct machine. The question is, who is responsible for issuing these certificates?

The tiger team decided that, first and foremost, the provider must ensure the safety of the patient's information. Whoever holds the data is responsible for protecting its safety. With respect to issuing digital credentials, providers can do that themselves or they may delegate it to an authorized credentialing service provider.

The team made the following specific recommendations:

- The responsibility for maintaining the privacy and security of a patient's record rests with the patient's providers. For functions like issuing digital credentials or verifying provider identity, providers may delegate that authority to authorized credentialing service providers.
- To provide physicians and hospitals (and the public) with some reassurance that this credentialing responsibility is being delegated to a "trustworthy" organization, the federal government (ONC) has a role in establishing and enforcing clear requirements and policies

about the credentialing process, which must include a requirement to validate the identity of the organization or individual requesting a credential.

- State governments can, at their option, also provide additional rules for these authorized credentialing service providers.

The Committee discussion that followed included these highlights:

- LaTanya Sweeney noted that the recommendations and the discussion are centered on one class of technical solutions that relate to message passing. She discussed a survey of about 50 companies around the country who have invested millions of dollars in NHIN solutions. Many communities are making technology-related decisions, and none of the technologies have had the benefit of going through NHIN Direct. She commented that there appears to be an “unfairness” related to the process in which companies that have innovative ideas are unable to participate in NHIN Direct.
- Gayle Harrell noted that with exchange categories/models C and D, the level of policy has to rise in order for the level of trust to be sufficient. Categories/models A and B are direct exchange, with no intermediary. Higher degrees of accountability are necessary with C and D.
- One Committee member suggested that it seems too definitive to simply recommend that ONC should “encourage” the use of categories/models A and B.
- David Blumenthal reminded the group that there are constituencies who are asking for advice and instructed on how best to proceed (even though this group does not have that authority). Many states are wishing that ONC would tell them exactly how they should resolve some of these privacy and security problems. ONC will have to make some of those decisions, and is seeking this Committee’s consensus advice. He asked HITPC members to keep in mind the time urgency, the need for states to begin to be active, and need for providers to have some confidence about the circumstances under which they can share information.
- LaTanya Sweeney expressed some frustration from the perspective of a computer scientist. In her field, they start by determining the requirements and the space of technical solutions, and they quickly rule out options. She suggested that if ONC starts off with an engineering requirements analysis (which has largely been done with the meaningful use work), within 1 month one or more useful solutions could be developed.
- One Committee member indicated that message handling categories/models A and B are necessarily cheaper, because they may be sending information that is “dirty” or unintelligible. There is a very big return on investment associated with checking to make sure the appropriate things are there/not there (as in category/model C).

Action Item #2: The Committee accepted the first set of Privacy and Security Workgroup tiger team recommendations (related to directed exchange), with the removal of the reference to the ONC “encouraging”

the use of message handling categories/models A and B. The Committee accepted the second set of tiger team recommendations as they stand.

8. Enrollment Workgroup Update

Enrollment Workgroup Chair Aneesh Chopra presented the list of Enrollment Workgroup members, noting that people who work in other industries understand data sharing models that can bring some perspective to the group. Also included is a robust group of federal partners, stakeholders from across the federal government. The group's charge is to inventory standards that are already in place, identify the gaps, and develop a set of processes to address those gaps. The Workgroup is focused on the following areas: (1) electronic matching across state and federal data, (2) retrieval and submission of electronic documentation for verification, (3) reuse of eligibility information, (4) capability for individuals to maintain eligibility information online, and (5) notification of eligibility.

The Workgroup needs to conceptualize standards that might be useful and work across a variety of use cases or architectures. The goal is to create a set of architectures that match up with HITPC and HITSC principles. The Enrollment Workgroup held its first public hearing, in which 2014 implementation was discussed. Examples at state and local levels were considered, and Workgroup members and others discussed how people are using web-based protocols. At its next meeting, Enrollment Workgroup members will be examining a particular use case.

The discussion that followed included these points:

- Aneesh Chopra noted that one of the Workgroup's questions for consideration may be how best to get hospital finance departments hooked into this idea so that they can assist in enrollment efforts.
- Gayle Harrell commented that the enrollment project is a real issue for states. Whether it is Medicaid eligibility, food stamps, or some other state-run program, the individual state bears responsibility for enrollment projects. She asked Aneesh Chopra whether he anticipates that this program will roll out and states will integrate into a system, although each state may implement their programs differently. Aneesh Chopra explained that this is why technology must be in support of policy, and not vice versa. Their process will need to include conveying to states "regardless of how it is technically done, you need to capture this person's name and confirm that they live in New Jersey [for example]. How you do that is open."
- Aneesh Chopra offered an example from the U.S. Postal Service (USPS), which has created a system to verify a person's address. Any group can adopt that system: a state, a commercial web site, etc. When the USPS designed this system, it did not presume how and in what manner it would be consumed. It had to keep the design simple and easy to replicate.
- Gayle Harrell reminded the Committee that with this enrollment effort comes very specific privacy issues. Different states have different requirements. A plethora of issues will have to be discussed, especially related to privacy issues.

- Charles Kennedy said that in the existing market where private insurers sell health insurance, people have to fill out medical information on their insurance applications. This represents a good source of information on the clinical side that should not be ignored.
- Aneesh Chopra offered another example of a design principle: students filling out student loan applications can go to the Internal Revenue Service web site and request that their tax information flow into the Department of Education student loan form. The IRS does not directly share that information with the Department of Education: the student controls when and if the data flows from one agency to the other. This is the type of process and information that the Enrollment Workgroup will be considering.

9. ONC Update: Temporary Certification Program

Steve Posnack of ONC reported that in early March, the Interim Final Rules for the temporary and permanent certification programs were published. ONC is starting with the temporary program first. The comment period for this temporary program ended on April 9, and the rule was written, cleared, and published in about 9 weeks.

The final rule was published on June 24 (the day before this meeting), representing the first significant step that will set in motion one of the processes that needs to be in place. regional extension centers can now start formulating their plans for helping organizations get to meaningful use. The rule establishes a process for the National Coordinator to use in authorizing organizations to test and certify EHRs. Also, it sets the parameters for the testing of EHR technology.

Each Committee member received a copy of the rule, including a list of all of the changes made between the initial proposed rule and the final rule. Steve Posnack called out a few of these changes:

- Remote testing certification is now listed as the minimum option for certification.
- There is a set of capabilities that must be present in order to meet meaningful use standards. There are numerous other capabilities that health care providers will actually need for their operation. This rule is primarily concerned with the former. Testers must be able simply to test against meaningful use certification criteria, and not a range of other services that do not specifically address meaningful use.
- Inherited certification will be possible when a certified system releases a new software version. The producer must attest that the updated version still meets the certification criteria.
- A list of certified EHRs will be made available.

Carol Bean of ONC explained that the temporary certification program is based on international standards and best practices that look at the entities providing the testing. Testers chosen for the temporary certification program are called ONC Authorized Testing and Certification Bodies

(ATCBs). ONC is currently in the final stages of creating the applications themselves. Already, the Office has received more than 30 requests for the applications. The form has multiple parts. Everyone will fill out Part 1. Part 2 will be filled out differently by different entities, depending on the scope of testing authorization they are seeking. The two parts can be submitted separately, but an application will not be complete until both parts 1 and 2 are received.

ONC will provide a decision to authorize (or not) a testing organization within 30 days. All applications will be reviewed by an internal review board. A list of authorized ATCBs will be provided on the ONC web site. By late summer, it is expected that some ATCBs will be in operation. There will be no limit on applicants, and no limit on the number of testing bodies that can be authorized. A new web site, called CHAPEL, will aggregate lists of certified products and technologies from the ATCBs.

10. Public Comment

Mark Siegel of GE Healthcare urged the Committee to give careful consideration to some timing issues with regard to NHIN Direct. ONC expects that testing and certification for the 2013/2014 period will need to begin by mid-2012. This is a concern, given that the next stage of meaningful use will begin in October, 2012 for hospitals. Inconsistently, the next set of standards criteria will be published in the summer of 2012. These dates, which were put in as projections, should be scrutinized to make sure that providers and vendors have what they need for safe and effective implementation.

SUMMARY OF ACTION ITEMS:

Action Item #1: The Committee approved the minutes from last HITPC meeting, held May 19, 2010, by consensus.

Action Item #2: The Committee accepted the first set of Privacy and Security Workgroup tiger team recommendations (related to directed exchange), with the removal of the reference to the ONC “encouraging” the use of message handling categories/models A and B. The Committee accepted the second set of tiger team recommendations as they stand.